REMARKS

In accordance with the foregoing, claim 13 has been amended and claim 27 has been added. Therefore, claims 1-6, 13-19, 24 and 27 are pending and claims 13-15 and 27 are under consideration, which is respectfully requested.

No new features and/or new matter have been added. Accordingly, entry and approval of claims 13 and 27 is respectfully requested.

I. AMENDMENT TO THE CLAIMS

Claim 13 has been amended to change the phrase "the functional starch powder comprises... starch particles with a particle size of 50 to 500 μm." Claim 13 now recites that "10% or more of all functional starch powder particles observable in the field of vision at a magnification of 600 are starch particles with a particle size of 50 to 500 μm." Antecedent basis may be found in the Published U.S. Patent Application (hereinafter "the Specification") of the present invention at paragraph [0061], lines 11-18. The other amendments to claim 13 have been made to clarify the claim language.

II. REJECTION UNDER 35 U.S.C. § 112

The Office Action rejects claim 13 under 35 U.S.C. § 112, first paragraph. The Office Action asserts claim 13 fails to comply with the written description requirement. Particularly, the Office Action asserts that the original disclosure does not describe heat-treating a starch raw material at a pressure less than atmospheric pressure. The Office Action acknowledges that the Specification provides support for "under reduced pressure" in paragraphs [0042] and [0068]. However, the Office Action "contends that 'reduced pressure' can be interpreted in many ways since applicants did not define the phrase with a point of reference in the original disclosure."

Applicants respectfully submit that the analysis of the Office Action is incomplete because other relevant parts of the Specification were not taken into consideration. The phrase "in a pressure less than atmospheric pressure" is further supported by Examples 2-6. In these examples, the pressure is reduced to 600 mmHg (0.79 atm) just before the starch raw material is heat treated. Examples 2-6 describe that the potato starch is packed in a stainless steel vat and then the pressure is reduced. The examples provide the "point of reference," which the Examiner argues is missing. That is, the examples clearly convey that the potato starch is

packed in the vat at atmospheric pressure. Accordingly, any reduction in the pressure results in a pressure less than atmospheric pressure.

Accordingly, amended claim 13 complies with the written description requirement under 35 U.S.C. § 112. Therefore, the rejection of claim 13 under 35 USC § 112 should be withdrawn, which is respectfully requested.

III. REJECTION UNDER 35 U.S.C. § 103

The Office Action rejects claims 13-15 and 24 under 35 U.S.C. § 103. The Office Action asserts that claims 13-15 and 24 are obvious over U.S. Patent 5,759,581 to Baensch et al. (hereinafter "Baensch") in view of US Patent 6,822,091 B1 to Kesselmans et al. (hereinafter "Kesselmans").

The Office Action asserts that the steps of the Baensch process are similar to the claimed process. The Office Action argues that any features of claim 13 that are undisclosed by Baensch would therefore be inherent in the Baensch starches.

i) Baensch

Before specifically addressing the claim limitations not taught by Baensch, it should be noted that the purpose for which the Baensch starches may be used and the swelling-related properties of the Baensch starches are clearly different from those of the functional starch particles of the present application. The Baensch reference is directed to a starch for use as a food additive which simulates dietary fat. To achieve this goal, the Baensch starch particles are made to be resistant to swelling or clumping. On the other hand, the application describes that the starch particles may be swollen to obtain sustained-release properties. See Specification at paragraph [0072], lines 1-6. Although the claims are not so restricted, the starch powder described in the present application may be used to form extended release medication tablets. For this purpose, the starch particles clump together around the active ingredient, are able to absorb significant quantities of water and withstand forces. In this manner, an extended period of time is required before the starch particles collapse and release the active ingredient.

The Office Action argues that the claimed "particle sizes are taught by Baensch et al. in overlapping manner." Specifically, the Office Action asserts that 10% of the Baensch starch particles are greater than 30 μm.

However, Baensh describes that 90% of the Baensch starch particles have a diameter in the range of about 5 to 30 μm and that the average diameter of particles is about 15 μm. See Baensch at column 2, lines 53-55. It is generally understood in the art that powders follow a

normal particle size distribution. Therefore, the particle size distribution of the Baensh starches follow a normal distribution wherein the mean is 15 μm and the dispersion is σ. From these values, Applicants estimate that only 0.3% or less of the Baensch particles would have a particle size of 50 μm or greater. Further, Baensch teaches away from producing starch powders where the fraction of particles larger than 50 μm is greater than 0.3%. At column 8, lines 8-14, Baensch specifically describes "it has also been shown that the addition of maltodextrin prior to drying hinders the swelling of the high-amylose starch granules during the heating steps, so that a narrower distribution of particle size is obtained and the further dispersion of the starch is facilitated, avoiding the formation of lumps." Baensch teaches adding maltodextrin prior to heating in order to narrow the particle size distribution and avoid the formation of lumps. A narrower particle size distribution could mean that even less than 0.3% of the Baensch particles would be 50 μm or larger.

In comparison, amended claim 13 clearly recites that "10% or more of all functional starch powder particles observable in the field of vision at a magnification of 600 are starch particles with a particle size of 50 to 500 μm." By controlling the particle size of the starch particles in the range of 50 to 500 μm, satisfactory sustained release properties may be obtained. See Specification at paragraph [0061], lines 21-38. Accordingly, it is clear that Baensch fails to teach or suggest the claimed particle size distribution.

The Office Action asserts that water retention capacity would be inherent in the Baensch starches.

Claim 1 recites a functional starch powder having a water retention capacity of 400% or more. The water retention capacity of the functional starch powder may have important consequences with respect to the ultimate properties of the functional starch powder. As the Specification explains in paragraph [0058]:

> when the water retention capacity is less than 400%, the starch powder is hydrated to form no gel, resulting in disintegration of tablets, or the starch powder cannot exhibit satisfactory release-sustaining properties because of rapid diffusion of an active ingredient(s) even when the starch powder forms a gel layer.

The Baensch starches do not possess the claimed water retention capacity. The Specification defines the water retention capacity "as the volume of pure water retained by starch after the centrifugation (2000G, 10 minutes) of a dispersion of 1 g of dry starch powder in pure water." See Specification at paragraph [0058]. Baensch is directed to a "food grade texture agent in the form of thermally stabilized swelling resistant" starch particles. See Baensch at

Abstract and column 2, lines 10-16 and 48-52. It is difficult to see how the Baensch starch particles could be both swelling resistant and have a water retention capacity of 400% according to the definition above. The water retention capacity is not inherent in Baensch.

ii) Baensch and Kesselmans do not Disclose the Claimed Amylose and Amylopectin.

The Office Action asserts that Baensch teaches an amylose content between 40 and 70%. The Office Action asserts that Kesselmans discloses potato starch granules containing about 20% amylose and 80% amylopectin.

However, amended claim 13 recites that "10 to 90% by weight of the total amylose and amylopectin in the functional starch powder is present on the exteriors of the starch particles." The Office Action makes no argument that Baensch and Kesselmans render obvious having 10 to 90% by weight of a total amount of amylose and amylopectin present on the exteriors of the starch particles. Further, Baensch and Kesselmans are silent about where amylose and amylopectin are located in the starch particles. Therefore, Baensch and Kesselmans fail to teach the claimed amounts of amylase and amylopectin present on the exteriors of the starch particles.

Although the claims are not limited to what is disclosed in the specification, paragraphs [0070] and [0071] of the present application describe one way the amylose and amylopectin are released to the exterior of the starch particles. These paragraphs describe that when the starch particles are heated in the presence of water, they expand, causing hydrogen bonds in the amylose and amylopectin to break, thereby releasing the amylose and amylopectin to the exterior of the starch particles. Baensch does not describe this or any other process to release a significant amount of amylose and amylopectin to the exterior of the starch particles. In fact Baensch avoids swelling of the starch particles.

Moreover, the Specification teaches that the amount of amylose and amylopectin may have important consequences for the ultimate properties of the functional starch powder. In paragraph [0072], the Specification emphasizes the importance of controlling the amount of amylose and amylopectin released to the exteriors of the starch particles within the range from 10 to 90% by weight in order to obtain satisfactory sustained release properties. Neither Baensch nor Kesselmans describes the relationship between the amount of amylose and amylopectin present on the exterior of the starch particles and the sustained-release properties of a functional starch powder. Therefore, Baensch and Kesselmans fail to suggest the claimed amounts of amylase and amylopectin present on the exteriors of the starch particles.

Kesselmans discloses that potato starch granules contain about 20% amylose and 80% amylopectin. However, Kesselmans is silent about where those amylose and amylopectin are present. On the other hand, in the present invention, 10 to 90% by weight of the total amylose and amylopectin in the functional starch powder is present on the exteriors of the starch particles. Further, Kesselmans does no provide any hint or reason suggesting that amylose and amylopectin should be on the exterior of the particles. For example, Kesselmans does not describe a relationship between the amount of amylose and amylopectin and release-sustaining properties. The present application, on the other hand, describes that if the amount of amylose and amylopectin released to the exteriors of the starch particles is controlled within a range of 10 to 90% by weight, satisfactory release-sustaining properties may be obtained.

iii) Collapse Time, & Gel Indentation Load are not Inherent.

The Office Action asserts that the Baensch process is extremely similar to the method of claim 13. The Office Action asserts that "water retention capacity, collapse time, and gel indentation load are [therefore] necessarily similar and would be inherent [in] the product."

As discussed above, there are several differences between claim 13 and the Baensch reference. The Baensch starches are used to simulate fat while the claimed functional starch powder may be used to obtain satisfactory sustained-release properties. The Baensch starch particles are resistant to swelling while the claimed functional starch powder may have a water retention capacity of 400%. Baensch does not disclose the claimed particle size distribution, and even teaches away from it. Finally, Baensch does not disclose or suggest any amount of amylose or amylopectin present on the exterior of starch particles. Given so many differences, it cannot be said that the claimed water retention capacity, the collapse time, or the gel indentation load are inherent to the Baensch compositions.

Accordingly, amended claim 13 is nonobvious over Baensch in view of Kesselmans. Therefore, the rejection of amended claim 13 under 35 U.S.C. § 103 should be withdrawn, which is respectfully requested. Further, Claims 14-15 and 24 depend from allowable amended claim 13. Therefore, the rejection of claims 14-15 and 24 under 35 U.S.C. § 103 should be withdrawn, which is respectfully requested.

IV. DISCUSSION WITH EXAMINER

On October 7, 2010, Examiner Kassa kindly discussed the application with the undersigned. Specifically, the comments in the Advisory Action were reviewed. Applicants argued that because the specification clearly uses the term "reduced" there is sufficient

antecedent support for a pressure less than atmospheric pressure. This reads on any reduction in the pressure. Perhaps the limitation is broad, but it does have antecedent support in the specification. New claim 27 contains the pressure less than atmospheric pressure language. Claim 13 has been amended based on the Examiner's suggestion in the Advisory Action.

Applicants also discuss paragraph [0061] of the application and the particle size limitations. It is firmly believed that paragraph [0061] enables the particle size limitation. The Examiner is requested to again review this matter.

V. CONCLUSION

There being no further outstanding objections or rejections, it is submitted that the application is in condition for allowance. An early action to that effect is courteously solicited.

If there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned to attend to these matters.

If there are any additional fees associated with filing of this Amendment, please charge the same to our Deposit Account No. 19-3935.

Respectfully submitted,

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Date: Oct 7 2010

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